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| INFORMATION | N DISCLOSURE |
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| STATEMENT E | SY APPLICANT |

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Sheet 1

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| Application Number | 10/533,041 | | | |
| Filing Date | December 14, 2005 | | | |
| First Named Inventor | Mark S. Roby | | | |
| Art Unit | 1796 | | | |
| Examiner Name | Benjamin Gillespie | | | |
| Attorney Docket Number | 2873 (203-3512 PCT US) | | | |

| | U.S. PATENT DOCUMENTS WITHOUT REFERENCES | | | | | | |
|------------|--|--|------------------|-----------------------------|---|--|--|
| Examiner | Cite | Document Number | Publication Date | Name of Patentee or | Pages, Columns, Lines, Where | | |
| nitials* N | No.1 | Number-Kind Code ² (f Interval) | MM-DD-YYYY | Applicant of Cited Document | Relevant Passages or Relevant Figures Appear | | |
| | | 3,773,595 | 11-20-1973 | BURBA ET AL. | | | |
| | | 4,323,491 | 04-06-1982 | VESELOVSKY ET AL. | | | |
| | | 4,804,691 | 02-14-1989 | ENGLISH ET AL. | | | |
| | | 5,166,300 | 11-24-1992 | RUMON ET AL. | | | |
| | | 5,169,720 | 12-08-1992 | BRAATZ ET AL. | , | | |
| | | 5,175,228 | 12-29-1992 | WANG ET AL. | | | |
| | | 5,462,536 | 10-31-1995 | BRAATZ ET AL. | | | |
| | | 6,162,241 | 12-19-2000 | COURY ET AL. | | | |
| | | 2004/0023842 | 02-05-2004 | PATHAK ET AL. | | | |
| | Ì | 2005/0266086 | 12-01-2005 | SAWHNEY | | | |

| | | FOREIGN I | PATENT DOC | UMENTS WITH REFERENCES | | |
|-----------------------|---------------------------------|-------------------------------|--------------------------------|--|---|----------------|
| Examiner Initials* | Cite Foreign Patent Document Pt | | Publication Date MM-DD-YYYY | Name of Patentee or Applicant of Cited Document | Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear | T ⁶ |
| | 1 | EP 0 077 192 A2 | 04-20-1983 | E.I. Du Pont De Nemours and Company | | |
| | | EP 1 391 205 A1 | 02-25-2005 | Aventis Behring GMBH | | X |
| - | | JP 2002060341 (Abstract Only) | 02-26-2002 | Terumo Corp. | | |

| OTHER DOCUMENTS | | | | |
|-----------------------|--------------|---|----|--|
| Examiner Initials* | Cite No.1 | | T² | |
| | | Copy of International Search Report from Application EP 07 00 1213 dated September 6, 2007. | | |
| | | Copy of International Search Report from Application EP 03 77 9244 dated September 26, 2007. | | |
| | | Copy of International Search Report from Application PCT/US2006/46553 dated October 31, 2007. | | |
| | | Copy of International Search Report from Application PCT/US2006/46554 dated October 31, 2007. | | |

| Examiner | /Benjamin Gillespie/ | Date Considered 01/29/2008 | 8 |
|----------|--|----------------------------|---|
| | : Initial if citation considered, whether or nor citation is in confo f not in conformance and not considered. Include copy of this for | | |

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Sheet 1

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| Complete if Known | | | | |
|-----------------------|------------------------|---------------|--|--|
| Application Number | 10/533,041 | | | |
| Filing Date | December 14, 2005 | | | |
| First Named Inventor | Mark Roby | | | |
| Art Unit . | 1711 | | | |
| Examiner Name | B.J. Gillespie | | | |
| Attomor Docket Number | 2072 /202 2512 DCT LIC | $\overline{}$ | | |

| | | | U. S. PATEN | DOCUMENTS | |
|-----------------------|--------------|--|--------------------------------|--|--|
| Examiner Initials* | Cite No.1 | Document Number Number-Kind Code ^{2 (f known)} | Publication Date MM-DD-YYYY | Name of Patentee or Applicant of Cited Document | Pages, Columns, Unes, Where Relevant Passages or Relevant Figures Appear |
| | | ^{US-} 3,773,595 | 11/20/1973 | Burba et al. | |
| | | ^{US-} 4,323,491 | 4/6/1982 | Veselovsky et al. | |
| | | US- | | | |
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| | | IGN PATENT DOCU | MENTS | | |
|--------------|---|---|---|--|---|
| Cite No.1 | | Publication Date | Name of Patentee or Applicant of Cited Document | Pages, Columns, Lines, Where Relevant Passages | |
| | Country Code ³ "Number ⁴ "Kind Code ⁸ (if known) | MM-DD-YYYY | • | Or Relevant Figures Appear | |
| | EP 0 007 192 | 4/20/1983 | | | |
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| | | | | | L |
| | | | | | <u> </u> |
| | | | | | L |
| | Cite No.1 | Country Code ³ "Number ⁴ "Kind Code ⁸ (if known) | Cite No. Poreign Patent Document Publication Date MM-DD-YYYY Country Code ³ "Number ⁴ "Kind Code ⁶ (if known) | Cite No.1 Publication Date Applicant of Cited Document Country Code3 Number 4 Kind Code5 (if known) Name of Patentee or Applicant of Cited Document MM-DD-YYYY | Cite No.1 Publication Date Applicant of Cited Document MM-DD-YYYY Mere Relevant Figures Appear Country Code ³ Number ⁴ 'Kind Code ⁶ (if known) Publication Date MM-DD-YYYY M-DD-YYYY Mere Relevant Figures Appear |

| Examiner | ID attends ON 1 to | Date | |
|-----------|----------------------|------------|------------|
| Signature | /Benjamin Gillespie/ | Considered | 01/31/2008 |

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Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number. Complete if Known Substitute for form 1449/PTO **Application Number** 10/533,041 Filing Date INFORMATION DISCLOSURE December 14, 2005 STATEMENT BY APPLICANT **First Named Inventor** Mark Roby Art Unit 1711 (Use as many sheets as necessary) Examiner Name B.J. Gillespie Attorney Docket Number Sheet 2 2873 US (203-3512 PCT US)

| Examiner | Cite | NON PATENT LITERATURE DOCUMENTS Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of | |
|-----------|------|--|----------------|
| Initials* | No.1 | the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published. | T ² |
| | | Europena Search Report (EP 03 77 9244 dated September 26, 2007) | |
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| Signature | /Benjamin Gillespie/ | Considered | 01/29/2008 |

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| Art Unit | 1711 | 7 | | |
| Examiner Name | Benjamin Gillespie | ٦. | | |
| Attorney Docket Number | 2873 (203-3512 PCT US) | 7 | | |

| | Cite | Document Number Number-Kind Code ^{2 (V Instance)} | Publication Date | Name of Patentee or Applicant of Cited Document | Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear |
|--------------|------|---|------------------|--|---|
| | No.1 | | | | |
| | | 5,717,030 | 02-10-1998 | Dunn et al. | |
| | · | 5,990,237 | 11-23-1999 | Bentley et al. | |
| | | 6,071,530 | 06-06-2000 | Polson | |
| | | 6,261,544 | 07-17-2001 | Coury et al. | |
| | | 6,495,127 | 12-17-2002 | Wallace et al. | |
| | | 6,582,713 | 06-24-2003 | Newell et al. | |
| | | 2003/0032734 | 02-13-2003 | Roby | - |
| | | 2004/0068078 | 04-08-2004 | Milbocker | |
| | | 2004/0198901 | 10-07-2004 | Graham et al. | |
| | | 2005/0004661 | 01-06-2005 | Lewis et al. | |
| | | 2005/0070913 | 03-31-2005 | Milbocker et al. | |
| | | 2005/0069573 | 03-31-2005 | Cohn et al. | |
| | | 2005/0129733 | 06-16-2005 | Milbocker et al. | |
| - | | 2005/0147647 | 07-07-2005 | Glauser et al. | • |

| OTHER DOCUMENTS | | | | |
|-----------------------|--------------|--|----|--|
| Examiner Initials* | Cite No.1 | | T² | |
| | | Copy of International Search Report from PCT/US06/47013 dated October 3, 2007. | | |
| | | Copy of International Search Report from PCT/US06/46558 dated November 9, 2007. | | |
| | | Copy of International Search Report from PCT/US06/46552 dated November 15, 2007. | | |
| | | Copy of International Search Report from PCT/US06/47023 dated November 21, 2007. | | |

| Examiner /Benjamin Gillespie/ | Date Considered | 01/29/2008 | | | | |
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